

REMARKS

Claim Status

Upon entry of the claim amendments and cancellations herein, Claims 1, 2, 4, 11, 14, 25, and 26 will be pending. Claims 5, 15, and 21 have been canceled. Claim 24 has been canceled in view of a previous restriction requirement. New Claims 25 and 26 have been added.

The Rejection Under 35 U.S.C. § 103(a)

Claims 1, 2, 4, 5, 11, 14, 15, 21, and 24 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,366,965 (“Strein”).

Strein is distinguished from the claims of the present invention based on the cyclical nature of bisphosphonate dosing relative to the continuous dosing recited in Claim 1 of the present invention and its dependents. Strein discloses a dosing regimen containing an inhibiting period and a rest period; the inhibiting period further contains at least two intermittent periods (see Strein, Column 3, lines 65 – 69). The bisphosphonate is dosed during only one day of the intermittent period (see Strein, Column 4, lines 4 – 6). The rest period lasts for 20 – 120 days, more preferably 50 – 100 days, more preferably about 60 – 84 days, and most preferably about 75 – 80 days (see Strein, Column 4, lines 10 – 12).

Moreover, it is only during the rest period, again lasting for 20 – 120 days, that Strein suggests use of a nutrient such as calcium or vitamin D. This administration is after the inhibiting period, during which bisphosphonate is dosed only one day of each intermittent period. Strein only discloses administration of a placebo during the remaining days of the inhibiting period.

Thus, Strein discloses a cyclical regimen in which a bisphosphonate is dosed on at least two days during an inhibiting period, wherein those two days are separated by dosing without a nutrient during the remaining days of the inhibiting period (a placebo may be dosed during these remaining days (see Strein, Column 5, lines 61 – 65); after that, no bisphosphonate is dosed during the rest period. As such, there are long periods within the inhibiting period that no bisphosphonate is dosed, followed by another long period over the entire rest period (20 – 120 days) in which no bisphosphonate is dosed, making up a cyclical dosing regimen.

In contrast to Strein, the claims of the present invention are directed to kits in which bisphosphonate is dosed in accordance with a continuous, *not cyclical*, regimen. See amended Claim 1 which directs administration of bisphosphonate and nutrient continuously. Moreover, Applicants have amended the claims herein to recite a more specific regimen in which the kit is arranged for once-weekly dosing of the bisphosphonate over a 28 day period of time by providing 4 unit doses of the bisphosphonate and 24 unit doses of the nutrient.

Moreover, to further address the Examiner's rejection, the claims have been amended such that the bisphosphonate and nutrient are arranged in order of their use across the blister card in accordance with either Figure 3 or Figure 5 as set forth in the present specification. As such, the claimed kit does indeed perform differently relative to the cited art, as the kit is specifically structured to dictate the continuous - - not cyclical - - dosing of the bisphosphonate and nutrient.

In view of the foregoing, Applicants assert that the claims as amended herein would not have been obvious in view of Strein and the rejection should be withdrawn.

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Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from Strein. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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